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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,786	04/06/2006	Stefan Golz	00497401108	8672
22907 7590 04/01/2008 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051				
EXAMINER				
SAIDHA, TEKCHAND				
ART UNIT		PAPER NUMBER		
1652				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/574,786

**Applicant(s)**

GOLZ ET AL.

**Examiner**

Tekchand Saidha

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.  
2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 21-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1-18 and 21-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date 6/28/2006  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Preliminary amendment files 4/6/2006 is acknowledged. Accordingly, claims 1-18 & 21-23 are present in this application.
2. Restriction is required under 35 U.S.C. 121 and 372.
3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 & 4-11, drawn to a method of screening for therapeutic agent useful in the treatment of a disease selected from the group consisting of cardiovascular diseases<sup>1</sup>, endocrinological diseases<sup>2</sup>, metabolic diseases<sup>3</sup>, cancer<sup>4</sup>, inflammation<sup>5</sup>, gastroenterological diseases<sup>6</sup>, hematological diseases<sup>7</sup>, respiratory diseases<sup>8</sup>, neurological diseases<sup>9</sup>, urological diseases<sup>10</sup> and reproduction disorders<sup>11</sup> in a mammal, comprising the steps of

- i) contacting a test compound with a mosaic serine protease polypeptide, and
- ii) **detecting binding** of said test compound to said mosaic serine protease polypeptide.

Group II, claim(s) 2-3, drawn to a method of screening for therapeutic agent useful in the treatment of a disease selected from the group consisting of cardiovascular diseases<sup>1</sup>, endocrinological diseases<sup>2</sup>, metabolic diseases<sup>3</sup>, cancer<sup>4</sup>, inflammation<sup>5</sup>, gastroenterological diseases<sup>6</sup>, hematological diseases<sup>7</sup>, respiratory diseases<sup>8</sup>, neurological diseases<sup>9</sup>, urological diseases<sup>10</sup> and reproduction disorders<sup>11</sup> in a mammal, comprising the steps of

- i) determining **activity** of a mosaic serine protease polypeptide at a certain concentration of a test compound or in the absence of said test compound, and
- ii) determining the activity of said polypeptide at a different concentration of said test compound.

Group III, claim(s) 12-17, drawn to a method of screening for therapeutic agent useful in the treatment of a disease selected from the

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group consisting of cardiovascular diseases<sup>1</sup>, endocrinological diseases<sup>2</sup>, metabolic diseases<sup>3</sup>, cancer<sup>4</sup>, inflammation<sup>5</sup>, gastroenterological diseases<sup>6</sup>, hematological diseases<sup>7</sup>, respiratory diseases<sup>8</sup>, neurological diseases<sup>9</sup>, urological diseases<sup>10</sup> and reproduction disorders<sup>11</sup> in a mammal, comprising the steps of

- i) contacting a test compound with a mosaic serine protease **polynucleotide**, and
- ii) **detecting binding** of said test compound to said mosaic serine protease polynucleotide.

Group IV, claim(s) 18, drawn to a method of diagnosing a disease selected from the group consisting of cardiovascular diseases<sup>1</sup>, endocrinological diseases<sup>2</sup>, metabolic diseases<sup>3</sup>, cancer<sup>4</sup>, inflammation<sup>5</sup>, gastroenterological diseases<sup>6</sup>, hematological diseases<sup>7</sup>, respiratory diseases<sup>8</sup>, neurological diseases<sup>9</sup>, urological diseases<sup>10</sup> and reproduction disorders<sup>11</sup> in a mammal, comprising the steps of:

- i) determining the amount of a mosaic serine protease polynucleotide in a sample taken from said mammal, .and ii) determining the amount of mosaic serine protease polynucleotide in healthy and/or diseased mammals.

Group V, claim(s) 21, drawn to pharmaceutical composition for the treatment of disease selected from the group consisting of cardiovascular diseases<sup>1</sup>, endocrinological diseases<sup>2</sup>, metabolic diseases<sup>3</sup>, cancer<sup>4</sup>, inflammation<sup>5</sup>, gastroenterological diseases<sup>6</sup>, hematological diseases<sup>7</sup>, respiratory diseases<sup>8</sup>, neurological diseases<sup>9</sup>, urological diseases<sup>10</sup> and reproduction disorders<sup>11</sup> in a mammal, comprising a therapeutic agent which regulates the activity of a serine protease polypeptide, wherein the therapeutic agent is-

- i) a small molecule,
- ii) an RNA molecule,
- iii) an antisense oligonucleotide,
- iv) a polypeptide,
- v) an antibody, or
- vi) a ribozyme

Group VI, claim(s) 22, drawn to pharmaceutical composition for the treatment of disease selected from the group consisting of cardiovascular diseases<sup>1</sup>, endocrinological diseases<sup>2</sup>, metabolic diseases<sup>3</sup>, cancer<sup>4</sup>, inflammation<sup>5</sup>, gastroenterological diseases<sup>6</sup>, hematological diseases<sup>7</sup>, respiratory diseases<sup>8</sup>, neurological diseases<sup>9</sup>,

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urological diseases<sup>10</sup> and reproduction disorders<sup>11</sup> in a mammal, comprising a mosaic serine protease polynucleotide.

Group VII, claim(s) 23, drawn to pharmaceutical composition for the treatment of disease selected from the group consisting of cardiovascular diseases<sup>1</sup>, endocrinological diseases<sup>2</sup>, metabolic diseases<sup>3</sup>, cancer<sup>4</sup>, inflammation<sup>5</sup>, gastroenterological diseases<sup>6</sup>, hematological diseases<sup>7</sup>, respiratory diseases<sup>8</sup>, neurological diseases<sup>9</sup>, urological diseases<sup>10</sup> and reproduction disorders<sup>11</sup> in a mammal, comprising a mosaic serine protease polypeptide.

For each of inventions I-VII above, restriction to one of the diseases (1)-(11) is also required; and in case of Group V, a further election of one of the therapeutic agents (i)-(vi) is also required.

4. The inventions listed as Groups I-VII and (1)-(11) and in case of Group V, a further election of one of the therapeutic agents (i)-(vi) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-VII and (1)-(11) appears to be that they all relate to mosaic serine protease. According to the international search report claims 1-26 lack novelty as being anticipated by Xiao et al. [WO 01/96538, 12/20/2001]. Therefore, Groups I-VII and (1)-(11) and/or (i)-(vi) share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups V-VII and (1)-(11) and/or (i)-(vi) do not share a special common structural or functional feature while, the methods of Groups I-IV do not use the same reagents or produce the same results. Accordingly, Groups I-VII and (1)-(11) and/or (i)-(vi) are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

7. Brief description of drawing is missing and is required.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tekchand Saidha/

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March 18, 2008